PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for* Melatonin Evolan 2 mg, 3 mg, 4 mg and 5 mg *film-coated tablets

This is a summary of the risk management plan (RMP) for Melatonin Evolan 2 mg, 3 mg, 4 mg and 5 mg film-coated tablets (hereafter referred to as melatonin film-coated tablets). The RMP details important risks of melatonin film-coated tablets, how these risks can be minimised, and how more information will be obtained about melatonin film-coated tablets' risks and uncertainties (missing information).

Melatonin film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how melatonin film-coated tablets should be used.

I. The medicine and what it is used for

Melatonin film-coated tablet is indicated for:

- Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.
- Short term treatment of jet lag in adults
  (See SmPC for full indication).

It contains melatonin as active substance and to be taken by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks when taking melatonin film-coated tablets, together with measures to minimise such risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of melatonin film-coated tablet is not yet available, it is listed under 'missing information' below.

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II.A List of important risks and missing information

Important risks of melatonin film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of melatonin film-coated tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected.

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

There is none important identified risk, important potential risk and missing information.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of melatonin film-coated tablets.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for melatonin film-coated tablets.

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